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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/615,157	07/13/2000	Niraj A. Shah	ACS-52045	4747

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EXAMINER

WEBB, SARAH K

ART UNIT PAPER NUMBER

3731

DATE MAILED: 09/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/615,157

Applicant(s)

SHAH ET AL.

Examiner

Sarah K Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 July 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Drawings*

1. The corrected or substitute drawings were received on 5/24/01. These drawings are approved by the draftsman.

### *Claim Objections*

2. Claims 2,3,4,6,7, 11 and 17 are objected to because of the following informalities:
  - “spines” in claims 2,3,6, and 7 should be changed to “splines” in order to comply with the specification and other claims.
  - “become” in line 2 of claim 4 should be “becomes”
  - claim 11 should have a period at the end instead of a comma
  - claim 17 is missing the word “assembly” after “filtering” in line 7

Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C.

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122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1-6, 8-14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,814,064 to Daniel et al.

The distal protection device of Daniel anticipates the limitations of the claims, as most clearly illustrated in Figures 16A and 16B. Guidewire (194), sheath (204), and filter (202) are shown here. The distal end of the sheath is attached to the guidewire. Daniels also includes a tubular shaft (178) and a plurality of struts (184), or splines, in the device, as shown in Figure 15. The filter allows blood to flow through, but captures emboli fragments (column 5, line 25). In lines 44-46 of column 9, Daniel explains that as the sheath is pulled proximally, it retains the filter in a collapsed position. He goes on to explain here that the sheath is formed of polymer material and filter is self-expanding. A hypotube (318) formed from nitinol is included in the filter device (column 12, line 31).

As shown in Figure 1, the filter is positioned downstream of the lesion. The operation of the filter device is described throughout the patent, and the steps include deploying the filter, using hypotubes, and withdrawing the sheath over the filter to capture emboli.

4. Claims 1,2,4,5,7-9,11,12,14,17-18 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,171,328 to Addis.

Addis anticipates all the limitations of claims 1-14 and 17-21. As shown in Figure 1A, a guidewire (29), tubular shaft (10), filter (20), sheath (36), and splines (23)

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are included. Addis explains that the sheath is made from a flexible polymer material (col 6, line 12). Figure 2 illustrates that the sheath retains the filter in a collapsed position. Addis explains that the filter can be formed of nitinol (column 3, line 5), which inherently makes the filter self-expanding. A recess is provided on part 40 of the shaft (Figure 1A). Figure 2 shows that in the collapsed position, the struts are received in the recess, and the filter has a low profile in the sheath.

Addis explains that the filter is positioned downstream of the lesion and expanded so that the edges make contact with the vessel wall (column 6, paragraph 3). In the following paragraph, Addis explains that interventional devices, or stents, may be placed in the vessel before the filter and captured emboli are contracted into the sheath. (See figure 5B)

5. Claims 1-6 and 10-15 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,171,327 to Daniel et al.

Daniel includes all the limitations of claims 1-6 and 8-15. Shown in Figure 1 are guidewire (26) with filter (21) attached distally and tubular shaft (12). Frame (24) and tails (28), or splines, are made of nitinol (column 4, line 45). This inherently means the filter assembly is self-expanding. Filter membrane (22) is made from flexible polymer (column 4, line 54). Figures 15 and 16 show a sheath (440 or 640) that is flared outwardly in the proximal direction and receives the filter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Addis in view of U.S. Patent No. 5,814,064 to Daniel.

As discussed above, Addis includes all the limitations of claims 17-21, but fails to fix the filter on a hypotube. Daniel teaches the use of a nitinol hypotube (318 or 322 in Figure 20A) on a distal protection device as an alternative to guidewire (14), where the hypotube has the same size as a guidewire and increased flexibility (column 13, lines 36-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the guidewire (14) of Addis with a hypotube, as taught by Daniel, as this forms a more flexible distal protection device.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- U.S. Patent No. 6,290,710 to Cryer includes all the limitations of the claimed invention
- U.S. Patent No. 6,383,206 to Gillick et al. – teaches a filter with sheath used in combination with a stent
- U.S. Patent No. 6,179,859 to Bates et al.- self-expanding filter made of Ni-Ti alloy
- U.S. Patent No. 6,383,193 to Cathcart et al. – self-expanding filter with retainer

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- U.S. Patent No. 5,911,734 to Tsugita et al – Figure 15A, Figure 12B

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 305-7554. The examiner can normally be reached on 8am-4:30pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Sarah K Webb  
Examiner  
Art Unit 3731

SW  
September 11, 2002



Michael Milano  
Supervisory Patent Examiner  
Art Unit 3700